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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,684	07/14/2003	Marc B. Garnick	PPI-111	8447

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,684	GARNICK, MARC B.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 11-23, 25-34, drawn to method of treating endometriosis using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

II. Claims 1, 3, 11-23, 25-33, 35, drawn to drawn to method of treating ovarian cancer using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

III. Claims 1, 4, 11-23, 25-33, 36, drawn to drawn to method of treating breast cancer using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

IV. Claims 1, 5, 11-23, 25-33, 37, drawn to drawn to method of treating polycystic ovary syndrome using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

V. Claims 1, 6, 11-23, 25-33, 38, drawn to drawn to method of treating uterine leiomata using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

VI Claims 1, 7, 11-23, 25-33, 39, drawn to drawn to method of treating dysfunctional uterine bleeding using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

VII. Claims 1, 8, 11-23, 25-33, 40, drawn to drawn to method of treating premenstrual syndrome using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

IX. Claims 1, 9, 11-23, 25-33, 41-45, drawn to drawn to method of treating vaginal bleeding using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

X. Claims 1, 9, 11-23, 25-33, 46, drawn to drawn to method of treating uterine fibroids using LHRH antagonist and estrogen receptor modulator that is raloxifene, classified in class 514, subclass 2.

XI. Claims 1-2, 11-22, 24, 25-34, drawn to method of treating endometriosis using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XII. Claims 1, 3, 11-22, 24, 25-33, 35, drawn to drawn to method of treating ovarian cancer using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XIII. Claims 1, 4, 11-22, 24, 25-33, 36, drawn to drawn to method of treating breast cancer using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XIV. Claims 1, 5, 11-22, 24, 25-33, 37, drawn to drawn to method of treating polycystic ovary syndrome using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XV. Claims 1, 6, 11-22, 24, 25-33, 38, drawn to drawn to method of treating uterine leiomata using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XVI Claims 1, 7, 11-22, 24, 25-33, 39, drawn to drawn to method of treating dysfunctional uterine bleeding using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XVII. Claims 1, 8, 11-22, 24, 25-33, 40, drawn to drawn to method of treating premenstrual syndrome using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XIX. Claims 1, 9, 11-22, 24, 25-33, 41-45, drawn to drawn to method of treating vaginal bleeding using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

XX. Claims 1, 9, 11-22, 24, 25-33, 46, drawn to drawn to method of treating uterine fibroids using LHRH antagonist and estrogen receptor modulator that is tamoxifen, classified in class 514, subclass 2.

Claims 1, 11-22 link(s) inventions I-XX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, 11-22. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Each invention in Group I-X or XI-XX have been restricted based on the disorder to be treated. The disorders recited in each Group is independent and distinct and would require a substantially different search. This is due to the different etiologies, different populations group associated with each disorder. For example, treatment of vaginal bleeding is significantly different from treatment of ovarian cancer or breast cancer. Even though each group utilizes similar active agents, the search would have be based the disorder to be treated. A search for one disorder would not lead o results of another.

The inventions of Groups I-X and XI-XX is independent and distinct because the two sets of groups utilize a structurally different estrogen receptor modulator. Raloxifene and tamoxifen are structurally distinct compounds that would require divergent searches. Even though some of the groups in I-X and XI-XX they may be classified in the same class and sub-class, the search would be based on the compounds and the diseases. Since the compounds used are structurally distinct and the disease to be treated are different form one another, as search for each group would be different.

Because these inventions are distinct for the reasons given above and the search required for each Group I-XX is different, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the LHRH antagonist to be used. Claim 19-20 recite a genus for the LHRH antagonist. Applicants are requested to elect a single disclosed species for the LHRH antagonist.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-46 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.